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AB

(FILE 'HOME' ENTERED AT 15:25:28 ON 25 FEB 2002)

FILE 'MEDLINE, CAPLUS, BIOSIS, SCISEARCH' ENTERED AT 15:25:44 ON 25 FEB 2002

L17078 S ADENO-ASSOCIATED (W) VIRUS OR AAV

21697 S CARDIOMYOCYTE L2

23 S L1 AND L2

12 DUP REM L3 (11 DUPLICATES REMOVED) L4

=> d au ti so ab 1-12 14

ANSWER 1 OF 12 CAPLUS COPYRIGHT 2002 ACS DUPLICATE 1 Kawada, Tomie; Nakazawa, Mikio; Nakauchi, Sakura; Yamazaki, Ken; ΑU Shimamoto, Ryoichi; Urabe, Masashi; Nakata, Jumi; Hemmi, Chieko; Masui, Fujiko; Nakajima, Toshiaki; Suzuki, Jun-Ichi; Monahan, John; Sato, Hiroshi; Masaki, Tomoh; Ozawa, Keiya; Toyo-Oka, Teruhiko

Rescue of hereditary form of dilated cardiomyopathy by rAAV-mediated ΤI somatic gene therapy: amelioration of morphological findings, sarcolemmal permeability, cardiac performances, and the prognosis of TO-2 hamsters

SO Proceedings of the National Academy of Sciences of the United States of America (2002), 99(2), 901-906 CODEN: PNASA6; ISSN: 0027-8424

The hereditary form comprises .apprxeq.1/5 of patients with dilated cardiomyopathy (DCM) and is a major cause of advanced heart failure. Medical and socioeconomic settings require novel treatments other than cardiac transplantation. TO-2 strain hamsters with congenital DCM show similar clin. and genetic backgrounds to human cases that have defects in the .delta.-sarcoglycan (.delta.-SG) gene. To examine the long-term in vivo supplement of normal .delta.-SG gene driven by cytomegalovirus promoter, we analyzed the pathophysiol. effects of the transgene expression in TO-2 hearts by using recombinant adenoassocd. virus vector. The transgene preserved sarcolemmal permeability detected in situ by mutual exclusivity between cardiomyocytes taking up i.v. administered Evans blue dye and expressing the .delta.-SG transgene throughout life. The persistent amelioration of sarcolemmal integrity improved wall thickness and the calcification score postmortem. Furthermore, in vivo myocardial contractility and hemodynamics, measured by echocardiog. and cardiac catheterization, resp., were normalized, esp. in the diastolic performance. Most importantly, the survival period of the TO-2 hamsters was prolonged after the .delta.-SG gene transduction, and the animals remained active, exceeding the life expectancy of animals without

transduction of the responsible gene. These results provide the first evidence that somatic gene therapy is promising for human DCM treatment,

L4ANSWER 2 OF 12 BIOSIS COPYRIGHT 2002 BIOLOGICAL ABSTRACTS INC.

ΑU Kawada, Tomie (1); Nakazawa, Mikio; Toyo-oka, Teruhiko

if the rAAV vector can be justified for clin. use.

Somatic gene therapy of dilated cardiomyopathy.

Folia Pharmacologica Japonica, (January, 2002) Vol. 119, No. 1, pp. 37-44.

print.

ISSN: 0015-5691.

AB The hereditary form of dilated cardiomyopathy (DCM) accounts for about 20%

of human DCM and is a major cause of heart failure. TO-2 strain hamsters show DCM, a gene deletion of delta-sarcoglycan (SG), loss of all four SGs,

alpha-, beta-, gamma- and delta-SG proteins, and are useful for developing

gene therapy of the hereditary DCM. The delta-SG is a component of dystrophin-associated glycoprotein complex that stabilizes sarcolemma. Four familial and sporadic DCM cases have been reported in human patients with the same delta-SG gene mutation. To establish the potential gene therapy of DCM, efficient and long-lasting transduction of the responsible

gene is mandatory, especially for improving the functional defect. Recombinant adeno-associated virus (rAAV)

vector with delta-SG gene was intramurally transfected to the TO-2 hearts at 5-weeks-old. The transfected myocardium revealed robust expression of both transcript and transgene after 10 and 20 weeks. Immunohistological analyses demonstrated re-expression of not only delta-SG but also the other SGs and normalization of the diameter of transduced cardiomyocytes without the pathogenicity. Hemodynamic studies revealed preferential amelioration of the diastolic indices. It suggests

novel strategy for the treatment of DCM and the rAAV vector is available for the treatment of several human diseases because of its safety and efficacy.

L4 ANSWER 3 OF 12 MEDLINE DUPLICATE 2

AU Kawada T; Sakamoto A; Nakazawa M; Urabe M; Masuda F; Hemmi C; Wang Y; Shin

W S; Nakatsuru Y; Sato H; Ozawa K; Toyo-oka T

TI Morphological and physiological restorations of hereditary form of dilated

cardiomyopathy by somatic gene therapy.

a

of

SO BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS, (2001 Jun 8) 284 (2) 431-5.

Journal code: 9Y8; 0372516. ISSN: 0006-291X.

AB TO-2 strain hamsters with dilated cardiomyopathy, gene deletion of delta-sarcoglycan (SG) and no expression of alpha-, beta-, gamma-, and delta-SG proteins are useful for developing the potential gene therapy of intractable heart failure. We prepared recombinant adeno-associated virus vector including normal delta-SG gene driven by CMV promoter and intramurally administered in vivo. The transfected myocardium induced robust expression of both transcript and transgene for 2/3 period of the animal's life expectancy. Immunostaining demonstrated reexpression of not only delta-SG but also other three SGs in

40% cells in the transfected region and normalization of the diameter of transduced cardiomyocytes. Hemodynamic study revealed preferential amelioration of the diastolic indices (LVEDP, the dP/dt(min) and CVP). These results provide the first evidence that supplementation

a specific gene with efficient and sustained transfection capability restores the genetic, morphological, and functional deteriorations. Copyright 2001 Academic Press.

- L4 ANSWER 4 OF 12 CAPLUS COPYRIGHT 2002 ACS
- AU Gao, Wenqian; Li, Xiaoying; Wu, Xiaobing; Pei, Xuetao; Li, Liang
- TI Study on transfected cardiomyocytes by recombinant adenovirus and adeno-associated virus
- SO Zhongguo Yingyong Shenglixue Zazhi (2001), 17(2), 157-160 CODEN: ZYSZE2; ISSN: 1000-6834
- AB Recombinant adenovirus (rAd) and adeno-assocd.

  virus were created, in which .beta.2-adrenergic receptors

  (.beta.2- AR) gene is under control of the cmv promotor, the cultured

neonate rat ventricular myocytes were infected by the two vectors, and the  $\ensuremath{\mathsf{I}}$ 

expression of .beta.2-AR on cultured neonate rat ventricular myocytes was assessed. RT-PCR demonstrated the presence of .beta.2-AR mRNA, protein immunoblots demonstrated the expression of the .beta.2-AR gene.

## According

to a ligand binding assay, the d. of .beta.--AR in the cardiomyocytes infected by rAd and rAAV had no difference, which was greater than that in the control. The results demonstrated that rAd vector and AAV vector transfected efficiently cardiomyocytes.

- L4 ANSWER 5 OF 12 SCISEARCH COPYRIGHT 2002 ISI (R)
- AU Aikawa R (Reprint); Snyder R; Huggins G S
- TI Cardiomyocyte-specific gene expression by recombinant adeno-associated virus containing the alpha myosin heavy chain promoter and enhancer
- SO CIRCULATION, (23 OCT 2001) Vol. 104, No. 17, Supp. [S], pp. 116-116. MA 560.

  Publisher: LIPPINCOTT WILLIAMS & WILKINS, 530 WALNUT ST, PHILADELPHIA, PA 19106-3621 USA.

ISSN: 0009-7322.

- L4 ANSWER 6 OF 12 BIOSIS COPYRIGHT 2002 BIOLOGICAL ABSTRACTS INC.DUPLICATE 3
- AU Gao Wen-qian (1); Li Xiaoying (1); Wu Xiao-bing (1)
- TI The study of beta2-AR and EGFP gene transferred into cardiomyocytes by AAV vector.
- SO Journal of Molecular and Cellular Cardiology, (June, 2001) Vol. 33, No. 6,

pp. A37. print.

Meeting Info.: XVII ISHR World Congress of the International Society for Heart Research Winnipeg, Canada July 06-11, 2001 ISSN: 0022-2828.

- L4 ANSWER 7 OF 12 MEDLINE DUPLICATE 4
- AU Maeda Y; Ikeda U; Oya K; Shimpo M; Ueno S; Urabe M; Kume A; Monahan J; Ozawa K; Shimada K
- TI Adeno-associated virus-mediated transfer of endothelial nitric oxide synthase gene inhibits protein synthesis of rat ventricular cardiomyocytes.
- SO CARDIOVASCULAR DRUGS AND THERAPY, (2001 Jan) 15 (1) 19-24. Journal code: 8712220. ISSN: 0920-3206.
- AB We investigated whether nitric oxide (NO) synthase gene transfer could attenuate growth of cultured cardiac myocytes. First, we investigated the effects of exogenous NO and cGMP analog on protein synthesis of cultured neonatal rat cardiac myocytes. The NO donor 3-morpholino-sydnonimine-hydrochloride (SIN-1) and 8-bromo-cGMP caused concentration-dependent decreases in phenylephrine-stimulated incorporation of 3H-leucine into cardiac myocytes. We then transferred endothelial constitutive NO synthase

(ecNOS) gene into cultured neonatal rat cardiac myocytes using adeno-associated virus (AAV)

vectors. ecNOS gene transfer into cardiac myocytes induced 140 kD ecNOS protein expression and significantly increased cGMP contents of myocytes compared with control cells. ecNOS gene transfer inhibited 3H-leucine incorporation into cardiac myocytes in response to phenylephrine, which was significantly recovered in the presence of the NOS inhibitor N(G)-monomethyl-L-arginine acetate. These results indicate that endogenously generated NO by ecNOS gene transfer using  ${\bf AAV}$ 

vectors inhibits the alpha-adrenergic agonist-induced cardiac protein synthesis at least partially via cGMP production.

- ANSWER 8 OF 12 CAPLUS COPYRIGHT 2002 ACS L4
- Leiden, Jeffrey M.; Svensson, Eric IN
- Efficient and stable in vivo gene transfer to cardiomyocytes TIusing recombinant adeno-associated virus vectors
- PCT Int. Appl., 20 pp. SO CODEN: PIXXD2
- AB Recombinant adeno-assocd. virus (rAAV) vectors are used to transduce cardiomyocytes in vivo by infusing the rAAV into a coronary artery or coronary sinus. RAAV infection is not assocd. with detectable myocardial inflammation or myocyte necrosis. Thus, rAAV is a useful vector for the stable expression of therapeutic genes in the myocardium and can be used to deliver genes for inducing angiogenesis, inhibiting angiogenesis, stimulating cell proliferation, inhibiting cell proliferation and/or treating or ameliorating other cardiovascular conditions.
- L4 ANSWER 9 OF 12 CAPLUS COPYRIGHT 2002 ACS
- Chien, Kenneth R.; Wang, Yibin; Evans, Sylvia IN
- ΤI Adenovirus vector for heart-specific gene expression and its use in gene therapy
- PCT Int. Appl., 33 pp. SO CODEN: PIXXD2
- A human type-5 recombinant adenovirus vector Ad/CG/ITR for heart-specific AB gene expression is constructed by using the promoter from the cardiomyocyte-restricted cardiac ankyrin repeat protein (CARP)in combination of the inverted terminal repeat (ITR) sequences from human adeno-assocd. virus (AAV). Using green fluorescent protein (GFP) as a marker gene, Ad/CG/ITR is shown to direct transgene expression to myocardial tissue in cultured cell lines, in the injected heart muscle and in developing mouse embryos (by microinjection into cardiac cavities). The inclusion of AAV ITR is required for tissue-specific expression and the gene expression is regulated at the transcription level. The promoters of other cardiac restricted genes are also suggested. These cardiac-specific adenovirus vector can be used in gene therapy of heart diseases.
- ANSWER 10 OF 12 CAPLUS COPYRIGHT 2002 ACS Chao, Lee; Chao, Julie L4
- TN
- Treatment of cardiac and renal disorders with atrial natriuretic peptide TI and tissue kallikrein gene therapy
- SO PCT Int. Appl., 120 pp. CODEN: PIXXD2
- AΒ The invention provides methods for delivering tissue kallikrein (a serine proteinase) and atrial natriuretic peptide (a hormone secreted by atrial cardiomyocytes) genes to cells via gene therapy mechanisms for the treatment of non-hypertension assocd. renal and cardiac disorders. Treatment occurs via administration of the invention to a subject having а
  - non-hypertension assocd. renal or cardiac disorder under conditions whereby the nucleic acid is expressed.
- ANSWER 11 OF 12 CAPLUS COPYRIGHT 2002 ACS L4
- IN Podsakoff, Gregory M.; Kessler, Paul D.; Byrne, Barry J.; Kurtzman, Gary
- ΤI Adeno-associated virus vectors for gene therapy of muscle disease

- SO U.S., 27 pp., Cont.-in-part of U.S. Ser. No. 588,355. CODEN: USXXAM
- AB The use of recombinant adeno-assocd. virus (
  AAV) virions for delivery of therapeutic genes to muscle is disclosed. The invention allows for the direct, in vivo injection of recombinant AAV virions into muscle tissue, as well as for the in vitro transduction of muscle cells that can subsequently be introduced into a subject for treatment. The invention provides for sustained, high-level expression of the delivered gene and for in vivo secretion of the therapeutic protein from transduced muscle cells such that systemic delivery is achieved. Adeno-assocd. virus can transform myocytes and cardiomyocytes with a lacZ reporter gene in vitro. Transformation of mouse myotubes and myoblasts with a virus carrying the human erythropoietin gene led to the synthesis of the protein by transformed cells for 6-8 wk. I.m. injection was mor effective

at transformation of muscle cells and tissues than was i.v. injection. Use of an AAV vector to deliver an acid .alpha.-glucosidase gene that could be used for therapy of cardiomyopathy assocd. with glycogen storage diseases is described. Mice inoculated i.m. with the virus produced elevated levels of the enzyme for 10 wk.

- L4 ANSWER 12 OF 12 MEDLINE DUPLICATE 5
- AU Svensson E C; Marshall D J; Woodard K; Lin H; Jiang F; Chu L; Leiden J M
- TI Efficient and stable transduction of cardiomyocytes after intramyocardial injection or intracoronary perfusion with recombinant adeno-associated virus vectors.
- SO CIRCULATION, (1999 Jan 19) 99 (2) 201-5. Journal code: DAW; 0147763. ISSN: 1524-4539.
- AB BACKGROUND: The delivery of recombinant genes to cardiomyocytes holds promise for the treatment of a variety of cardiovascular diseases. Previous gene transfer approaches that used direct injection of plasmid DNA or replication-defective adenovirus vectors have been limited by low transduction frequencies and transient transgene expression due to immune responses, respectively. In this report, we have tested the feasibility

using intramyocardial injection or intracoronary infusions of recombinant adeno-associated virus (rAAV) vectors to program transgene expression in murine cardiomyocytes in vivo.

METHODS AND RESULTS: We constructed an rAAV containing the LacZ gene under

the transcriptional control of the cytomegalovirus (CMV) promoter (AAVCMV-LacZ). We then injected 1x10(8) infectious units (IU) of this virus into the left ventricular myocardium of adult CD-1 mice. Control hearts were injected with the AdCMV-LacZ adenovirus vector. Hearts harvested 2, 4, and 8 weeks after AAVCMV-LacZ injection demonstrated stable beta-galactosidase (beta-gal) expression in large numbers of cardiomyocytes without evidence of myocardial inflammation or myocyte necrosis. In contrast, the AdCMV-LacZ-injected hearts displayed transient beta-gal expression, which was undetectable by 4 weeks after injection. Explanted C57BL/6 mouse hearts were also perfused via the coronary arteries with 1.5x10(9) IU of AAVCMV-LacZ and assayed 2, 4, and

weeks later for beta-gal expression. beta-Gal expression was detected in <1% of cardiomyocytes at 2 weeks after perfusion but was detected in up to 50% of cardiomyocytes 4 to 8 weeks after perfusion. CONCLUSIONS: Direct intramyocardial injection or coronary artery perfusion with rAAV vectors can be used to program stable transgene

expression in cardiomyocytes in vivo. rAAV appears to represent

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of

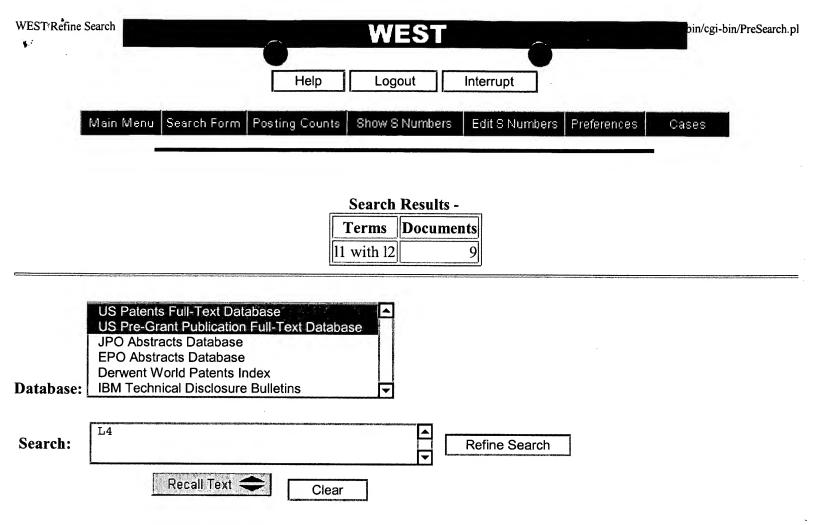
a useful vector for the delivery of therapeutic genes to the myocardium.

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     Efficient and stable in vivo gene transfer to cardiomyocytes
TT
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     Leiden, Jeffrey M.; Svensson, Eric
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     Arch Development Corp., USA
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     PCT Int. Appl., 20 pp.
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ΤI
     Adenovirus vector for heart-specific gene expression and its use in gene
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IN
     Chien, Kenneth R.; Wang, Yibin; Evans, Sylvia
PA
     Regents of the University of California, USA
     PCT Int. Appl., 33 pp.
     CODEN: PIXXD2
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    Treatment of cardiac and renal disorders with atrial natriuretic peptide
    and tissue kallikrein gene therapy
    Chao, Lee; Chao, Julie
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    MUSC Foundation for Research Development, USA
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    PCT Int. Appl., 120 pp.
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    Adeno-associated virus vectors for gene
    therapy of muscle disease
    Podsakoff, Gregory M.; Kessler, Paul D.; Byrne, Barry J.; Kurtzman, Gary
IN
PA
    Avigen, Inc., USA; Johns Hopkins University
    U.S., 27 pp., Cont.-in-part of U.S. Ser. No. 588,355.
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## Search History

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**END OF SEARCH HISTORY** 

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Aug 23, 2001

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TITLE: Methods of altering cardiac cell phenotype

Full Title Citation Front Review Classification Date Reference Sequences Attachments Claims KVMC Draw Desc Image

2. Document ID: US 20010001661 A1

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May 24, 2001

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DOCUMENT-IDENTIFIER: US 20010001661 A1

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TITLE: Methods for delivering DNA to the bloodstream using recombinant adeno-associated virus

vectors

Full Title Citation Front Review Classification Date Reference Sequences Attachments Claims KMC Draw. Desc Image

☐ 3. Document ID: US 6335011 B1

L4: Entry 3 of 9

File: USPT

Jan 1, 2002

US-PAT-NO: 6335011

DOCUMENT-IDENTIFIER: US 6335011 B1

TITLE: Methods for delivering DNA to muscle cells using recombinant adeno-associated virus virions

to treat lysosomal storage disease

Full Title Citation Front Review Classification Date Reference Sequences Attachments Claims KMC Draw. Desc Image

☑ 4. Document ID: US 6306830 B1

L4: Entry 4 of 9

File: USPT

Oct 23, 2001

US-PAT-NO: 6306830

DOCUMENT-IDENTIFIER: US 6306830 B1

TITLE: Gene therapy for congestive heart failure

Full Title Citation Front Review Classification Date Reference Sequences Attachments Claims KWIC Drawl Desc Image

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L4: Entry 5 of 9

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Aug 28, 2001

US-PAT-NO: 6281200

DOCUMENT-IDENTIFIER: US 6281200 B1

TITLE: Functional characterization of the C-C chemokine-like molecules encoded by molluscum

contagiosum virus types 1 and 2

Full Title Citation Front Review Classification Date Reference Sequences Attachments Claims KMC Draw. Desc Image

☐ 6. Document ID: US 6211163 B1

L4: Entry 6 of 9

File: USPT

Apr 3, 2001

US-PAT-NO: 6211163

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TITLE: Methods for delivering DNA to the bloodstream using recombinant adeno-associated virus

vectors

Full Title Citation Front Review Classification Date Reference Sequences Attachments Claims KMC Draw. Desc Image

☐ 7. Document ID: US 6165754 A

L4: Entry 7 of 9

File: USPT

Dec 26, 2000

US-PAT-NO: 6165754

DOCUMENT-IDENTIFIER: US 6165754 A

TITLE: Method of expressing an exogenous nucleic acid

Full Title Citation Front Review Classification Date Reference Sequences Attachments

KMMC Draw Desc Image

8. Document ID: US 5962313 A

L4: Entry 8 of 9

File: USPT

Oct 5, 1999

US-PAT-NO: 5962313

DOCUMENT-IDENTIFIER: US 5962313 A

TITLE: Adeno-associated virus vectors comprising a gene encoding a lyosomal enzyme

Full Title Citation Front Review Classification Date Reference Sequences Attachments

KWMC | Draww Desc | Image

9. Document ID: US 5858351 A

L4: Entry 9 of 9

File: USPT

Jan 12, 1999

US-PAT-NO: 5858351

DOCUMENT-IDENTIFIER: US 5858351 A

TITLE: Methods for delivering DNA to muscle cells using recombinant adeno-associated virus vectors

ull Title Citation Front Review Classification Date Reference Sequences Attachments

KWIC Draw, Desc Image

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